

Attorney Docket No.: DEX-0117
Inventors: Salceda et al.
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This listing of the claims will replace all prior versions and listings of claims in the application:

Listing of the claims:

Claims 1-2 (canceled)

/ Claim 3 (currently amended): A method for diagnosing the presence of breast cancer in a patient comprising:

(a) determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in cells, tissues or ~~body fluids~~ whole blood in a patient; and

(b) comparing the determined levels of BCSG polynucleotide with levels of BCSG polynucleotide in cells, tissues or ~~body fluids~~ whole blood from a normal human control, wherein an increase in determined levels of BCSG polynucleotide in said patient versus normal human control is associated with the presence of breast cancer and wherein the BCSG polynucleotide comprises SEQ ID NO: 1 or 2 ~~or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1 or 2.~~

2 ✓ Claim 4 (currently amended): A method of diagnosing metastases of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in cells, tissues, or ~~body fluids~~ whole blood from said patient; and

(c) comparing the determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissue, or ~~body fluids~~ whole blood of a normal human control, wherein

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an increase in determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO: 1 or 2 ~~or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1 or 2.~~

3 Claim 5 (currently amended): A method of staging breast cancer in a patient having breast cancer comprising:

- (a) identifying a patient having breast cancer;
- (b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in a sample of cells, tissue, or ~~body fluids~~ whole blood from said patient; and
- (c) comparing determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or ~~body fluids~~ whole blood of a normal human control, wherein an increase in determined BCSG polynucleotide levels in said patient versus the normal human control is associated with breast cancer which is progressing and a decrease in the determined BCSG polynucleotide levels is associated with breast cancer which is regressing or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO: 1 or 2 ~~or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1 or 2.~~

4 Claim 6 (currently amended): A method of monitoring breast cancer in a patient for the onset of metastasis comprising:

- (a) identifying a patient having breast cancer that is not known to have metastasized;

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(b) periodically determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in samples of cells, tissues, or ~~bodily fluids~~ whole blood from said patient; and

(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or ~~bodily fluids~~ whole blood of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO: 1 or 2 ~~or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1 or 2.~~

5 Claim ~~1~~ (currently amended): A method of monitoring a change in stage of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer;

(b) periodically determining levels of Breast Cancer Specific Genes (BCSG) polynucleotide in cells, tissues, or ~~bodily fluids~~ whole blood from said patient; and

(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or ~~bodily fluids~~ whole blood of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which is progressing in stage and a decrease is associated with breast cancer which is regressing in stage or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO: 1 or 2 ~~or a polynucleotide which~~

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~~hybridizes under stringent conditions to the antisense
sequence of SEQ ID NO: 1 or 2.~~

Claims 8-18 (canceled)

6 Claim ~~19~~ (currently amended): The method of ~~claim 18~~
claim 3 wherein the BCSG polynucleotide comprises SEQ ID
NO:1.

7 Claim ~~20~~ (currently amended): The method of ~~claim 18~~
claim 3 wherein the BCSG polynucleotide comprises SEQ ID
NO:2.

Claim 21-22 (canceled)

8 Claim ~~23~~ (currently amended): The method of ~~claim 22~~
claim 4 wherein the BCSG polynucleotide comprises SEQ ID
NO:1.

9 Claim ~~24~~ (currently amended): The method of ~~claim 22~~
claim 4 wherein the BCSG polynucleotide comprises SEQ ID
NO:2.

Claim 25-26 (canceled)

10 Claim ~~27~~ (currently amended): The method of ~~claim 26~~
claim 5 wherein the BCSG polynucleotide comprises SEQ ID
NO:1.

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11 Claim ~~28~~ (currently amended): The method of ~~claim 26~~
claim 5 wherein the BCSG polynucleotide comprises SEQ ID
NO:2.

Claim 29-30 (canceled)

12 Claim ~~31~~ (currently amended): The method of ~~claim 30~~
claim 6 wherein the BCSG polynucleotide comprises SEQ ID
NO:1.

13 Claim ~~32~~ (currently amended): The method of ~~claim 30~~
claim 6 wherein the BCSG polynucleotide comprises SEQ ID
NO:2.

Claim 33-34 (canceled)

14 Claim ~~35~~ (currently amended): The method of ~~claim 34~~
claim 7 wherein the BCSG polynucleotide comprises SEQ ID
NO:1.

15 Claim ~~36~~ (currently amended): The method of ~~claim 34~~
claim 7 wherein the BCSG polynucleotide comprises SEQ ID
NO:2.

Claim 37 (canceled)

16 Claim ~~38~~ (currently amended): A method for diagnosing
the presence of breast cancer in a patient comprising:
(a) determining levels of Breast Cancer Specific
Gene (BCSG) polynucleotide in cells, tissues or ~~body~~
fluids whole blood in a patient; and

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(b) comparing the determined levels of BCSG polynucleotide with levels of BCSG polynucleotide in cells, tissues or ~~body fluids~~ whole blood from a normal human control, wherein an increase in determined levels of BCSG polynucleotide in said patient versus normal human control is associated with the presence of breast cancer and wherein the BCSG polynucleotide comprises SEQ ID NO: 18 ~~or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 18.~~

17 Claim 36 (currently amended): A method of diagnosing metastases of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in cells, tissues, or ~~body fluids~~ whole blood from said patient; and

(c) comparing the determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissue, or ~~body fluids~~ whole blood of a normal human control, wherein an increase in determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO: 18 ~~or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 18.~~

18 Claim 40 (currently amended): A method of staging breast cancer in a patient having breast cancer comprising:

(a) identifying a patient having breast cancer;

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(b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in a sample of cells, tissue, or ~~body fluids~~ whole blood from said patient; and

(c) comparing determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or ~~body fluids~~ whole blood of a normal human control, wherein an increase in determined BCSG polynucleotide levels in said patient versus the normal human control is associated with breast cancer which is progressing and a decrease in the determined BCSG polynucleotide levels is associated with breast cancer which is regressing or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO: 18 ~~or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 18.~~

19 Claim 41 (currently amended): A method of monitoring breast cancer in a patient for the onset of metastasis comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) periodically determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in samples of cells, tissues, or ~~body fluids~~ whole blood from said patient; and

(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or ~~body fluids~~ whole blood of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG

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polynucleotide comprises SEQ ID NO:18 ~~or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:18.~~

20 Claim 42 (currently amended): A method of monitoring a change in stage of breast cancer in a patient comprising:

- (a) identifying a patient having breast cancer;
- (b) periodically determining levels of Breast Cancer Specific Genes (BCSG) polynucleotide in cells, tissues, or ~~bodily fluids~~ whole blood from said patient; and
- (c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or ~~bodily fluids~~ whole blood of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which is progressing in stage and a decrease is associated with breast cancer which is regressing in stage or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO:18 ~~or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:18.~~

21 Claim 43 (previously presented): The method of claim 3 wherein levels of BCSG polynucleotide are determined in cells.

22 Claim 44 (previously presented): The method of claim 3 wherein levels of BCSG polynucleotide are determined in tissues.

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23 Claim 45 (currently amended): The method of claim 3 wherein levels of BCSG polynucleotide are determined in ~~body fluids~~ whole blood.

Claim 46 (canceled)

24 Claim 47 (previously presented): The method of claim 4 wherein levels of BCSG polynucleotide are determined in cells.

25 Claim 48 (previously presented): The method of claim 4 wherein levels of BCSG polynucleotide are determined in tissues.

26 Claim 49 (currently amended): The method of claim 4 wherein levels of BCSG polynucleotide are determined in ~~body fluids~~ whole blood.

Claim 50 (canceled)

27 Claim 51 (previously presented): The method of claim 5 wherein levels of BCSG polynucleotide are determined in cells.

28 Claim 52 (previously presented): The method of claim 5 wherein levels of BCSG polynucleotide are determined in tissues.

29 Claim 53 (currently amended): The method of claim 5 wherein levels of BCSG polynucleotide are determined in ~~body fluids~~ whole blood.

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Claim 54 (canceled)

30 Claim ~~55~~ (previously presented): The method of claim 6 wherein levels of BCSG polynucleotide are determined in cells.

31 Claim ~~56~~ (previously presented): The method of claim 6 wherein levels of BCSG polynucleotide are determined in tissues.

32 Claim ~~57~~ (currently amended): The method of claim 6 wherein levels of BCSG polynucleotide are determined in ~~body fluids~~ whole blood.

Claim 58 (canceled)

33 Claim ~~59~~ (previously presented): The method of claim 7 wherein levels of BCSG polynucleotide are determined in cells.

34 Claim ~~60~~ (previously presented): The method of claim 7 wherein levels of BCSG polynucleotide are determined in tissues.

35 Claim ~~61~~ (currently amended): The method of claim 7 wherein levels of BCSG polynucleotide are determined in ~~body fluids~~ whole blood.

Claim 62 (canceled)

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36 Claim 63 (previously presented): The method of claim 38 wherein levels of BCSG polynucleotide are determined in cells.

37 Claim 64 (previously presented): The method of claim 38 wherein levels of BCSG polynucleotide are determined in tissues.

38 Claim 65 (currently amended): The method of claim 38 wherein levels of BCSG polynucleotide are determined in ~~bodily fluids~~ whole blood.

Claim 66 (canceled)

39 Claim 67 (previously presented): The method of claim 39 wherein levels of BCSG polynucleotide are determined in cells.

40 Claim 68 (previously presented): The method of claim 39 wherein levels of BCSG polynucleotide are determined in tissues.

41 Claim 69 (currently amended): The method of claim 39 wherein levels of BCSG polynucleotide are determined in ~~bodily fluids~~ whole blood.

Claim 70 (canceled)

42 Claim 71 (previously presented): The method of claim 40 wherein levels of BCSG polynucleotide are determined in cells.

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43 Claim 72 (previously presented): The method of claim 40 wherein levels of BCSG polynucleotide are determined in tissues.

44 Claim 73 (currently amended): The method of claim 40 wherein levels of BCSG polynucleotide are determined in ~~bodily fluids~~ whole blood.

Claim 74 (canceled)

45 Claim 75 (previously presented): The method of claim 41 wherein levels of BCSG polynucleotide are determined in cells.

46 Claim 76 (previously presented): The method of claim 41 wherein levels of BCSG polynucleotide are determined in tissues.

47 Claim 77 (currently amended): The method of claim 41 wherein levels of BCSG polynucleotide are determined in ~~bodily fluids~~ whole blood.

Claim 78 (canceled)

48 Claim 79 (previously presented): The method of claim 42 wherein levels of BCSG polynucleotide are determined in cells.

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49 Claim 80 (previously presented): The method of claim 42 wherein levels of BCSG polynucleotide are determined in tissues.

50 Claim 81 (currently amended): The method of claim 42 wherein levels of BCSG polynucleotide are determined in ~~bodily fluids~~ whole blood.

Claim 82 (canceled)